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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,790	01/30/2001	Endre Markovits Schersl	22106965.104181	2203

51738 7590 07/27/2006

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EXAMINER
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COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/772,790		SCHERSL, ENDRE MARKOVITS	
	<b>Examiner</b>		<b>Art Unit</b>	
	Abigail M. Cotton		1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 70-82 is/are pending in the application.
- 4a) Of the above claim(s) 74-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-73 and 81-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This office action is in response to the amendment submitted on June 8, 2006. Claims 70-82 are pending in the application, with claims 74-80 being withdrawn as drawn to a non-elected invention. Accordingly, claims 70-73 and 81-82 are being examined on the merits herein.

The objection to claims 71-72 on the basis of failing to further limit the subject matter of the previous claim is being withdrawn in view of Applicant's amendments to the claims. The objection to claim 70 due to incorrect spelling is also being withdrawn in view of the amendment to the claim. However, claim 71 is being newly objected to due to a grammatical error in the claim.

The rejections of claims 71 and 72 under 35 U.S.C. 112, second paragraph, as having a lack of antecedent basis, is being withdrawn in view of Applicant's amendments to the claims.

The rejection of claims 70-73 under 35 U.S.C. 103(a) as being unpatentable over Breivik et al, Horrobin, Granja et al, Levin et al. and Bundgaard has been withdrawn in view of Applicant's remarks submitted June 8, 2006. In particular, Applicant's argue that one of ordinary skill in the art would not have been motivated to provide a compound that is an ester of a polyunsaturated fatty acid such as those claimed, with a

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long-chain fatty alcohol such as those claimed, because while the references teach the beneficial therapeutic effects of polyunsaturated fatty acids and long chain fatty alcohols, or short-chain esters thereof, when administering the fatty acid or fatty alcohol separately, the references do not teach or suggest that an ester formed of the fatty acid and fatty alcohols as claimed could be cleaved in vivo to provide the same benefits.

While Bundgaard teaches that prodrug forms of carboxylic acids can include ester forms, Applicants have rebutted the assertion that this teaching of Bundgaard renders obvious the formation of long chain fatty alcohol ester "prodrugs" of the long chain fatty acids, by providing examples of esters of carboxylic acids, such as olestra and esters of beta-sitostanol, that are not believed to be hydrolysable in vivo.

Accordingly, it is considered that one of ordinary skill in the art would not have been motivated to prepare a composition having the claimed ester based on the teachings of the references as cited, because one of ordinary skill in the art would not have had a reasonable expectation of success of forming a compound capable of hydrolyzing in vivo to give the desired beneficial effects that are taught by the references for the individual fatty acid and fatty alcohol.

However, upon further consideration, a new ground(s) of rejection is being made. The claims are being rejected as follows.

### ***Claim Objections***

Claim 71 is objected to due to a grammatical error. In particular, claim 71 recites "the composition according to claim 70 *wherein the* further comprising one or more food substances." The Examiner respectfully suggests amending claim 71 to delete the phrase "wherein the" such that the claim reads "the composition according to claim 70 further comprising one or more food substances" (strikethrough added.)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70 and 81-82 are rejected under 35 U.S.C. 102(b) as being anticipated by over EP 0 910 955 to Hebpurn et al, published April 28, 1999.

Hebpurn et al. teaches blends of wax-esters with beneficial health properties that can comprise wax-esters derived from linear alcohols and linear carboxylic acids, either of them having at least 8 carbon atoms (see abstract, in particular.) Hebpurn et al. teaches that preferred acid residues are long chain polyunsaturated fatty acids such as

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arachidonic acid, EPA or DHA, and also teaches that acids such as oleic acid and/or linoleic acid can be used (see paragraph 0005, in particular.) Hebpurn et al. teaches that the long chain alcohol can contain at least 18 carbon atoms (see paragraph 0005-0007, in particular.)

Hebpurn et al. exemplifies a composition comprising behenyl linoleate/oleate made by reacting behenyl alcohol (docosanol) with fatty acids from the hydrolysis of sunflower oil (oleic and linoleic acids) (see paragraphs 0021-0023.) Accordingly, Hebpurn et al. teaches a composition having an ester of linoleic acid with docosanol, and thus meets the limitation of claim 70. As linoleic acid is a C18 acid, the composition of Hebpurn et al. also meets the limitation of having an ester of a carboxylic acid with 4 to 22 atoms of carbon with docosanol, and thus also meets the limitations of claims 81-82.

It is respectfully pointed out that the recitation that the composition is for "lowering LDL-cholesterol levels or elevating HDL cholesterol levels in the blood of a mammal" as in claims 1 and 81 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand

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alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.)

Claims 70 and 81-82 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/56883 to Maria Teresa Tacconi, published December 17, 1998.

Tacconi teaches that wax esters enriched with omega-3 unsaturated fatty acids can be used as drug and food additives (see abstract, in particular.) Tacconi teaches that the esters are formed from acids such as eicosapentaenoic acid and docosahexaenoic acid (see page 1, lines 21-28, in particular.) Tacconi teaches that the wax esters are prepared by reacting fatty acid esters with a methyl or ethyl alcohol moiety in a transesterification process with an alcohol (see column 3, lines 24-31, in particular), where the alcohol can comprise from 12 to 40 carbon atoms (see page 4, lines 1-10, in particular.)

Tacconi exemplifies forming such a wax ester by a transesterification of a fish oil ester having EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) with behenyl alcohol (docosanol) (see Example 1, page 11, in particular.) Accordingly, Tacconi teaches a composition having an ester of eicosapentaenoic acid and docosahexaenoic acid with docosanol, and thus meets the limitation of claim 70. As eicosapentaenoic acid and docosahexaenoic acid are C4-C22 acids, the composition of

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Tacconi also meets the limitation of having an ester of a carboxylic acid with 4 to 22 atoms of carbon with docosanol, and thus also meets the limitations of claims 81-82.

It is respectfully pointed out that the recitation that the composition is for "lowering LDL-cholesterol levels or elevating HDL cholesterol levels in the blood of a mammal" as in claims 1 and 81 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 910 955 to Hebpurn et al, published April 28, 1999.



Hebpurn et al. is applied as discussed above, and teaches a composition having a blend of wax esters derived from linear alcohols and linear carboxylic acids having at least 8 carbon atoms (see abstract, in particular), and further exemplifies a composition having behenyl alcohol (docosanol) esters of oleic and linoleic acid (see paragraphs 0021-0023, in particular.)

Hebpurn et al. does not specifically exemplify providing the behenyl linoleate in a food product, as recited in claims 71-73.

However, Hebpurn et al. teaches that the wax esters of the invention can be used as a fat replacement, and can be used in combination with triglycerides such as vegetable triglycerides and oils (see paragraph 0010, in particular.) Hebpurn et al. teaches that examples of foods into which the wax esters can be incorporated include ice creams, mayonnaise, spreads, and others (see paragraph 0013, in particular.) Thus, Hebpurn et al. teaches that the wax esters in general can be incorporated into food products such as those recited in claims 71-72.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the specific wax esters in the food products as taught by Hebpurn et al, because Hebpurn teaches that esters of carboxylic acids and fatty alcohols such as those claimed can be provided as fat replacements in food

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products. Thus, one of ordinary skill in the art would have been motivated to provide the esters of long chain carboxylic acids and fatty alcohols in a food product with the expectation of providing a suitable fat substitute.

Regarding claim 73, Hebpurn et al. teaches the wax esters can be provided in a spread with 90-10% water content (see paragraph 0013, in particular), and thus teaches providing the excipient that is water in the compositions.

Claim 71 is rejected under 35 U.S.C. 103(a) as being obvious over WO 98/56883 to Maria Teresa Tacconi, published December 17, 1998.

Tacconi is applied as discussed for claims 70 and 81-82 above, and teaches wax esters of omega-3 unsaturated fatty acids and long chain fatty alcohols as claimed.

Tacconi also exemplifies a wax ester of docosanol and EPA and DHA.

Tacconi does not specifically exemplify a food substance combined with the specific ester that meets the limitations of the claims, as recited in claim 71.

However, Tacconi does teach that the wax esters can be incorporated as drug and food additives for pharmaceutical and dietetic-alimentary purposes (see abstract, in particular.) Thus, Tacconi teaches that the wax esters can be provided with food substances, as recited in claim 71.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the specific wax esters in the food products as taught by Tacconi, because Tacconi teaches that esters of carboxylic acids and fatty alcohols such as those claimed can be provided as additives in food products and for dietetic-alimentary purposes. Thus, one of ordinary skill in the art would have been motivated to provide the esters of long chain carboxylic acids and fatty alcohols in a food product with the expectation of providing a suitable additive that can also provide dietetic-alimentary benefits.

### ***Response to Arguments***

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

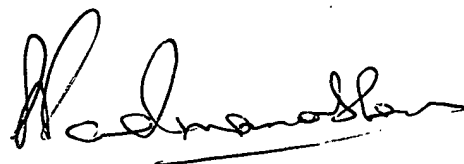
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line underneath.

**SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER**